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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10 055,749	01 22 2002	Christopher Meyer	3781-0102P	7350

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EXAMINER

GUO, LYNDAT

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02 12 2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055.749

Applicant(s)

MEYER, CHRISTOPHER

Examiner

Lynda T Guo

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 7-11 and 30, drawn to a method of treating a microorganism infection in a patient by inhibiting an enzyme involved in energy storage or utilization, classified in class 424 or 514, subclass unknown.
 - II. Claims 2-3, 7-11 and 30, drawn to a method of treating a microorganism infection in a patient by inhibiting production of ADP-glucose, classified in class 424 or 514, subclass unknown.
 - III. Claims 4, 7-11 and 30, drawn to a method of treating a microorganism infection in a patient by inhibiting the chain elongation of ADP glucose, classified in class 424 or 514, subclass unknown.
 - IV. Claims 5, 7-11 and 30, drawn to a method of treating a microorganism infection in a patient by inhibiting the activity of glycogen synthase, classified in class 424 or 514, subclass unknown and/or class 435, subclass 193.
 - V. Claims 6, 7-11 and 30, drawn to a method of treating a microorganism infection in a patient by inhibiting the activity of ADP glucose pyrophosphorylase, classified in class 424 or 514, subclass unknown, and/or class 435, subclass 197.
 - VI. Claim 12, drawn to a pharmaceutical composition comprising adenosine boranodiphosphoglucose, classified in class 514, subclass 46.
 - VII. Claim 13, drawn to a pharmaceutical composition comprising an inhibitor of ADP-glucose pyrophosphorylase, classified in class 514, subclass 47.

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- VIII. Claim 14, drawn to a pharmaceutical composition comprising an inhibitor of glycogen synthase, classified in class 514, subclass unknown.
- IX. Claims 15-17, drawn to a method of identifying a compound capable of inhibiting the growth of pathogenic microorganisms comprising the identification of an enzyme important to energy storage or utilization, classified in class 435, subclass 4.
- X. Claims 18 and 28, drawn to a method of identifying a compound capable of inhibiting the growth of pathogenic microorganisms comprising the identification of a compound that inhibits the conversion of α -glucose-1-phosphate + ATP into ADP-glucose+Ppi, classified in class 435, subclass 15.
- XI. Claims 19 and 28, drawn to a method of identifying a compound capable of inhibiting the growth of pathogenic microorganisms comprising the identification of a compound that inhibits the chain elongation of ADP glucose, classified in class 435, subclass 14.
- XII. Claims 20, 22, 24, and 26-28, drawn to a method of identifying a compound capable of inhibiting the growth of pathogenic microorganisms by inhibiting ADP-glucose pyrophosphorylase activity, classified in class 435, subclasses 19 and 21.
- XIII. Claims 21, 23, 25, and 28, drawn to a method of identifying a compound capable of inhibiting the growth of pathogenic microorganisms by inhibiting glycogen synthase activity, classified in class 435, subclass 15.

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XIV. Claims 29 and 31, drawn to a composition capable of inhibiting the growth of pathogenic microorganisms, classified in class 514, subclass unknown.

The inventions are distinct, each from the other because of the following reasons:

2. The methods of Inventions I-V are each different and patentably distinct. The Inventions are different and patentably distinct because each has materially different requirements and the steps involved for each is different. Specifically, Invention I inhibits energy storage or utilization by the microorganism; The mechanism of Invention II is to inhibit ADP-glucose production; Invention III inhibits the elongation of ADP glucose (i.e. inhibits formation of glucans); Invention IV inhibits the activity of glycogen synthase; and Invention V inhibits the activity of ADP glucose pyrophosphorylase. Each of the mechanisms is therefore different and distinct because different enzymes in the microorganism are targeted, which means a different compound is used in each treatment method.
3. The compositions of Inventions VI, VII, VIII, and XIV are each compositionally, structurally and materially different and therefore patentably distinct from one another. For example, the composition of Invention VI comprises adenosine boranodiphosphoglucose, which is materially and structurally from the ADP-glucose pyrophosphorylase inhibitor of Invention VII and the glycogen synthase inhibitor of Invention VIII.
4. The methods of Inventions IX-XIII are each different and patentably distinct. The Inventions are different and patentably distinct because each has materially different requirements and the steps involved for each is different. Specifically, Invention IX involves the identification of an enzyme important in energy storage or utilization by the microorganism and then screening for a compound that inhibits the identified enzyme; the method of Invention X is

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only for screening compounds that inhibit the conversion of α -glucose-1-phosphate + ATP into ADP-glucose+Ppi; the method of Invention XI screens for compounds that inhibit the elongation of ADP glucose; the method of Invention XII screens for compounds that inhibit ADP glucose pyrophosphorylase; and the method of Invention XIII screens for compounds that inhibits glycogen synthase. The target of each method is materially different; therefore, the candidates involved in the screening process will also be different materially and structurally, as well as in their mechanisms of action.

5. The compositions of Inventions VI-VIII and XIV and the methods of Inventions I-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating microorganism infection can use a materially different product, such as one that affects the integrity of the microorganism's cell wall.

6. The methods of treating in Inventions I-V and the methods of compound screening for Inventions IX-XIII are different and patentably distinct from one another. The methods are different and distinct because the methods involve different materials and steps and the results are different. For example, the methods of treatment comprise the administration of a compound to an animal so that growth of a pathogenic microorganism is inhibited. The screening methods comprise the use of numerous candidate compounds, the affect on the microorganism being unpredictable, and the method itself could involve various assays for enzyme activity (such as ELISA or other assays).

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7 The methods of inventions IX-XIII and the compositions of Inventions VI-VII and XIV are different and patentably distinct. They are patentably distinct because the methods do not require the composition for patentability and vice versa. Specifically, the compositions can be used to probe the reaction mechanism of the enzymes that they inhibit. The subject matters of the two sets of inventions are clearly divergent and therefore patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

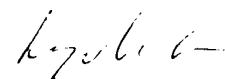
9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

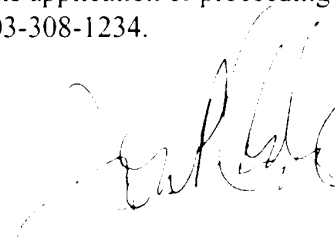
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Tue - Fri and alternate Mondays (9:00am - 7:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Lynda T Guo
Patent Examiner
February 7, 2003



Jon P. Weber, Ph.D.
Primary Examiner